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10/803,672	03/18/2004	Tsutomu Okada	17548	5931

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EXAMINER	
YABUT, DIANE D	

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3734	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/803,672	OKADA, TSUTOMU	
	Examiner	Art Unit	
	Diane Yabut	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,9-12,14-16 and 18-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,9-12,14-16 and 18-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/21/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's amendment received on 5 March 2007. The examiner acknowledges the amendments made to the claims.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 21 May 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 9-12, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by **Matsuno et al.** (U.S. Patent No. **5,766,184**).

Claims 1, 9, and 10: Matsuno et al. discloses a flexible insertion tube, or flexible insertion means, **28** capable of being inserted into a cavity of a living body, a flexible wire **37**, or elongate means, formed of stainless steel, which is pliable and therefore having ductility, wherein "wire" is taken to mean "a length of material," and movably

passed through the insertion tube for advance and retreat, and a junction provided on the distal end portion of the wire, detachably coupled with a clip **45** located at the distal end portion of the insertion tube, and pliable enough to follow up deformation of the insertion tube, or follows the curve in the tube, and effects grasping operation and disengaging operation of the clip (Figure 14 and col. 3, lines 63-64 and col. 5, lines 8-11).

Claim 2: Matsuno et al. discloses the junction having a looped portion formed by turning one end part of the wire, wherein "looped" is taken to mean "curved," the looped portion being coupled with the clip (Figure 5A).

Claim 11: Matsuno et al. discloses a flexible insertion tube **28** capable of being inserted into a cavity of a living body, a manipulating member **33** which is passed through the insertion tube for advance and retreat and moves with respect to the insertion tube, thereby effecting grasping operation and disengaging operation of a clip located at the distal end portion of the insertion tube, a flexible connecting member **37**, formed of stainless steel, and therefore having ductility, extending from the clip, having one end and the other end, the one end being coupled to the distal end of the manipulating member and the other end detachably coupled to the clip, and pliable enough to follow up deformation of the insertion tube (Figure 14 and col. 3, lines 63-64 and col. 5, lines 8-11).

Claim 12: Matsuno et al. discloses the connecting member **37** having a flexible wire, wherein "wire" is taken to mean "a length of material," and a junction provided on the

distal end portion of the wire, detachably coupled to the clip, and pliable enough to follow up deformation of the insertion tube (Figure 14).

Claim 15: Matsuno et al. discloses a flexible insertion tube **28** capable of being inserted into a cavity of a living body, a manipulating member, or wire, **33** which is passed through the insertion tube for movement and is moved with respect to the insertion tube, thereby effecting grasping operation and disengaging operation of a clip **45** located at the distal end portion of the insertion tube, and a coupling member **37** which is provided on the distal end of the manipulating member, is coupled to a wire **33** extending from the clip and pliable enough to follow up deformation of the insertion tube, effects grasping operation of the clip, and can leave the clip when the manipulating member is hauled with a tractive effort great enough to leave the clip (Figure 14 and col. 3, lines 63-64 and col. 5, lines 8-11).

Claim 16: Matsuno et al. discloses a flexible tube sheath **3** penetrated by the insertion tube **28** for advance and retreat, the tube sheath being capable of storing the clip located at the distal end portion of the insertion tube (Figure 14, col. 3, lines 52-55).

4. Claims 5 and 6 are rejected under 35 U.S.C. 102(a) as being anticipated by **Muramatsu et al.** (U.S. Patent No. **20020133178**).

Clam 5: Muramatsu et al. discloses a flexible insertion tube **1** capable of being inserted into a cavity of a living body, a flexible wire **4** having pliability and movably passed through the insertion tube, a clip **3** located at the distal end portion of the insertion tube and having a hook **3f**, and a junction **4a** provided on the distal end portion of the wire, detachably coupled with the hook of the clip, and pliable enough to follow up

deformation of the insertion tube (Figures 2A, Figures 3A-3B, page 3, paragraph 84, page 4, paragraph 97).

Claim 6: Muramatsu et al. discloses a clip retainer pipe **2** which covers the proximal end portion of the clip when the wire is hauled whereby the clip is manipulated and the retainer pipe covers the hook when the hook is deformed and disengaged from the wire (Figure 2A).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 3, 4, 7, 8, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Matsuno et al.** (U.S. Patent No. **5,766,184**) in view of **Muramatsu et al.** (U.S. Patent No. **20020133178**).

Claims 3 and 14: Matsuno et al. discloses the claimed device, except for the wire having a turn portion coupled to the clip and a weak portion formed of at least parts of doubled wire portions on two opposite sides and intertwined so as to loosen when the wire is hauled with a tractive effort great enough to leave the clip.

Muramatsu et al. teaches a wire **4** having a turn portion coupled to the clip and a weak portion **4a** formed of at least parts of doubled wire portions of the wire on two opposite sides and may be intertwined so as to loosen when the wire is hauled with a

tractive effort great enough to leave the clip (Figure 3B and page 9, paragraph 179). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a wire with a turn portion and an intertwined weak portion, as taught by Muramatsu et al., to Matsuno et al. since it was known in the art that a closed loop turn portion with an intertwined weak portion at the end of a wire coupled to a clip provides the option of using more controlled force when hauling a wire, as opposed to using an open loop hook which may lead to undesired release of the clip.

Claims 4 and 13: Matsuno et al. discloses the claimed device, except for the junction having a weak portion which breaks when the wire is hauled with a tractive effort great enough to leave the clip.

Muramatsu et al. teaches a junction having a weak portion **14a** which breaks when the wire is hauled with a tractive effort great enough to leave the clip (page 9, paragraph 178). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a junction having a weak portion which breaks, as taught by Muramatsu et al., to Matsuno et al. since it was known in the art that the detachment between a manipulating member and a clip may be ensured and more efficient when there is breakage after applying a tractive force as opposed to maneuvering the manipulating member in relation to the clip for detachment, which involves more precision and is time consuming.

Claims 7 and 8: Matsuno et al. discloses the claimed device, except for a clip setting portion which is provided on the distal end of the insertion tube that detachably stores the clip, controls the clip in open-close action and the clip is plastically deformed as the

wire is manipulated, the clip setting portion having a slit from which the clip detaches after the clip is plastically deformed.

Muramatsu et al. teaches a clip setting portion **2** which is provided on the distal end of the insertion tube that detachably stores the clip, and controls the clip in open-close action and the clip is plastically deformed as the wire is manipulated, the clip setting portion having a slit, or aperture at its distal end, from which the clip detaches after the clip is plastically deformed (Figures 2A-2C). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a clip setting portion with a slit and the clip to be plastically deformed, as taught by Muramatsu et al., to Matsuno et al. since it was known in the art that protection and actuation is necessary for a clip before and after useage in engaging with tissue and plastic deformation of a clip ensures a permanent position of the clip in order for the clip to maintains its function.

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Matsuno et al.** (U.S. Patent No. **5,766,184**) in view of **Sugiyama et al.** (U.S. Patent No. **20020177861**).

Claim 17: Matsuno et al. discloses the claimed device, except for the part of the insertion tube which is situated behind the clip and exposed from the distal end of the tube sheath when the clip projects from the tube sheath forms a curvedly raised portion. Sugiyama et al. teaches a part of an insertion tube **130** which is situated behind a clip **110** and is adapted to be exposed from the distal end of a tube sheath **150** when the clip projects from the tube sheath forming a curved portion (Figure 46). Although

Sugiyama et al. does not show a curved portion that is raised, it would have been obvious to one of ordinary skill to use a curvedly raised portion since it was known in the art that insertion tubes are formed of flexible material and therefore they may accommodate any curves, raised or lowered, while being maneuvered through a body lumen.

8. Claims 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Matsuno et al.** (U.S. Patent No. **5,766,184**), as applied to Claims 1 and 11 above, and further in view of **Foerster** (U.S. Pub. No. **20020026201**).

Claims 18-22: Matsuno et al. discloses the claimed device except for the manipulating member or flexible wire has a turn portion coupled to the clip and a weak portion formed of at least parts of doubled wire portions on two opposite sides and deformed so as to loosen when the manipulating member is hauled, and the junction or flexible connecting member both made of flexible wire being integrally formed with the flexible wire or manipulating member.

Foerster teaches a manipulating member or flexible wire **56a** has a turn portion coupled to a clip **12a** and a weak portion formed of at least parts of doubled wire portions on two opposite sides and deformed so as to loosen, or "to free from restraint" or break, when the manipulating member is hauled, and the junction or flexible connecting member both made of flexible wire being integrally formed with the flexible wire or manipulating member (Figures 9-12). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a weak portion on the

manipulating member, as taught by Foerster, to Matsuno et al. in order to facilitate the deployment of the clip with the manipulating member without using a second manipulating member or instrument to release the clip.

Response to Arguments

9. Applicant's arguments filed 5 March 2007 have been fully considered but they are not persuasive.

10. The applicant argues that the plate 37 of Matsuno, which is a thin band plate of stainless steel has limited pliability in the thickness direction and is not pliable in the width direction. The examiner disagrees. Stainless steel is well known in the art for having high ductility and may be manipulated or deformed in various directions. Also, it is noted that the features upon which applicant relies (i.e., the plate's or flexible wire's pliability in the width direction) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER